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NAIMA
NORTH AMERICAN INSULATION
MANUFACTURERS ASSOCIATION

VIA E-MAIL AND OVERNIGHT MAIL

May 22, 2009

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Health Sciences
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RE: Comments of the North American Insulation Manufacturers Association ("NAIMA")

Dear Dr. Lunn:

INTRODUCTION

The North American Insulation Manufacturers Association ("NAIMA"), a trade association representing the manufacturers of glass wool insulation in the United States and throughout North America, is pleased to present the following comments on the Draft Background Document for glass wool fibers (74 Fed. Reg. 15,983 (April 8, 2009)).[1]

NAIMA filed its Petition for Delisting Glass Wool (respirable size) from the Report on Carcinogens ("RoC") with the National Toxicology Program ("NTP") on January 28, 2002. The basis for NAIMA's Petition for Delisting is found in the International Agency for Research on Cancer's ("IARC") decision to change (from its earlier 1987 review and 1988 Monograph) the classification of "glass wool insulation." After examining the substantial body of science, IARC classified glass wool insulation in Group 3.[2] At the same time, IARC classified "special purpose

[1] The background document is titled "Report on Carcinogens Background Document for Glass Wool Fibers." The current NTP listing is for "glasswool (respirable size)." The nomenclature selected for the title of the background document reflects the current terminology recognized by IARC in its 2002 Monograph and includes the two separate categories of "glass wool fibers," 1) insulation wool, and 2) special purpose fibers. For clarity, NAIMA will throughout its comments refer to the category of glass wool fibers that make up the insulation wool category as "glass wool insulation."

[2] International Agency for Research on Cancer, *IARC Monographs on the Evaluation of Carcinogenic Risks to Humans: Man-Made Vitreous Fibres*, Vol. 81 (Lyon, France: WHO/IARC, 2002) ("IARC Monograph 81"). (http://monographs.iarc.fr/ENG/Monographs/vol81/mono81.pdf) IARC classified "Glasswool" in its 1988 Monograph. In 2002, IARC recognized the need to separate "glasswool," previously put together, into two categories – insulation wool and special purpose fibers. IARC stated in its 2002 Monograph: "Most glass wool has

glass fibers" in Group 2B. Later, NIEHS nominated special purpose fibers for listing in the RoC, relying on the same IARC decision that changed the classification of glass wool insulation and created a separate listing for special purpose fibers. NIEHS subsequently requested that the nomination of special purpose fibers be characterized as "certain glass fibers."

IARC's 2001 reclassification of glass wool insulation fibers to Group 3 concluded that the human data remained "inadequate," but that the animal data were no longer "sufficient;" instead, IARC reclassified the animal data as "limited." IARC also determined that mechanistic consideration regarding fiber biosolubility provided additional scientific support for changing glass wool insulation's classification from Group 2B, *possibly carcinogenic to humans,* to Group 3, *not classifiable as to its carcinogenicity to humans.*

NAIMA's comments respond to both the Draft Background Document for glass wool and the *Federal Register* notice announcing the availability of the Draft Background Document. NAIMA's comments demonstrate that the extensive published research relied upon by IARC, the Agency for Toxic Substances and Disease Registry ("ATSDR"), and others establishes that glass wool insulation (respirable size) does not meet the criteria for either human or animal evidence required for listing in the RoC. Therefore, "glass wool (respirable size)" should be removed from the NTP's RoC to accurately reflect the current state of the science. NAIMA's comments will not focus on the special purpose fibers nomination by NIEHS other than to describe the distinction between special purpose fibers and glass wool insulation fibers.

TWO SEPARATE NOMINATIONS ARE BEFORE THE EXPERT PANEL

The Draft Background Document does not adequately describe the procedural history of the Petitions being considered by NTP. It acknowledges (p.1) the NAIMA nomination for delisting glass wool, but does not mention the NIEHS nomination of special purpose fibers. The two nominations must be analyzed separately and distinctly from one another. The terms used to identify the glass wool nomination for delisting have evolved in the past several years. Initially, NAIMA's Petition for Delisting was characterized as "glass wool (respirable size)," the term used in the prior RoC. With the addition of the NIEHS nomination, the nominations were merged into one category entitled "Certain Glass Wool Fibers" (see 70 Fed. Reg. 60,548, 60,552 (October 18, 2005)). The NTP website currently identifies the two nominations under the single heading "Glass Wool Fibers."

In a November 9, 2005, letter to NAIMA (Attachment 1), NTP clarified its intention regarding the two nominations:

> [b]ased on the initial NAIMA nomination for delisting glass wool (respirable size) from the Report on Carcinogens (RoC), it is the NTP's intention to review the

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been used for a variety of insulation applications. An additional category has been used to group those glass fibres produced by flame attenuation for special applications. This category, termed 'special-purpose fibres' in Figure 1 and Table 1, includes, for example, fibres such as E-glass and 475-glass used for high-efficiency air filtration media, acid battery separators and certain fine-diameter glass fibres." IARC Monograph 81, p. 52.

> current listing of glass wool (respirable size) to determine if this listing should remain in or be removed from the RoC. This review will be part of the consideration of the certain glass wool fibers nomination. As indicated in the October 18, 2005 Federal Register (70 Fed. Reg. 60,552) the basis of the certain glass wool fibers nomination is the recent International Agency for Research on Cancer (IARC) finding of limited evidence of carcinogenicity in animals for insulation glass wool and its evaluation as an IARC Group 3 (not classifiable as to its carcinogenicity to humans), and the finding of sufficient evidence of carcinogenicity in animals for special-purpose glass fibers (IARC Monograph Vol. 81, 2002).

This clarification is provided so that the Expert Panel understands that NAIMA's Petition for Delisting Glass Wool (respirable size) is separate from the NIEHS nomination to list "special purpose fibers." More importantly, it frames the scope of NAIMA's Petition for Delisting. In 1988, IARC classified "glasswool" as Group 2B, possibly carcinogenic based on inadequate human data and sufficient animal data. IARC's 1988 classification thus had no need to separate glass wool insulation from special purpose fibers. "Glasswool" included all glass fibers, except continuous glass filament fibers.

In 1994, NTP, citing the 1988 IARC decision, classified "glasswool (respirable size)" as "reasonably anticipated to be carcinogenic based on sufficient evidence of carcinogenicity of glasswool in experimental animals" and "inadequate evidence of carcinogenicity of glasswool in humans." NTP did not define, and had no need to define, "glasswool (respirable size)," but NTP, like IARC, considered the term inclusive of all glass fibers with the exception of continuous glass filaments.

In October 2001, IARC recognized that insulation glass wool and special purpose fibers were both glass wools, but IARC distinguished the two based on animal data. The best description of IARC's 2001 decision is provided by Robert Baan and Yann Grosse of IARC:

> The general evaluation of the carcinogenic hazard of 'glass wool' was made by the Working Group in 1987 on the basis of the combined data for insulation glass wool and various other types of glass fibre . . . . By making a distinction between glass wool used for insulation and 'special purpose' glass fibres, the Working Group in 2001 reached more precise evaluations for these different materials.[3]

This explains the basis for NAIMA's Petition to Delist "glass wool (respirable size)." In essence, NAIMA's Petition is asking NTP to recognize that there is a class of glass wool fibers that do not meet NTP's criteria for listing as "reasonably anticipated to be carcinogenic." That class of glass wool fibers is referred to as glass wool insulation. NAIMA is asking NTP to address that issue by delisting glass wool (respirable size). NIEHS' nomination to list special

[3] Baan, R.A., Grosse, Y., Man-made mineral (vitreous) fibres: evaluations of cancer hazards by the IARC Monographs Programme, *Mutation Research* 553 (2004) 43–58, p. 51. These authors, IARC Monograph staff members, explain in detail the 1988 and 2001 IARC reviews and the specific bases for the decisions made.

purpose fibers is then the appropriate avenue in which to classify the specific subgroup which IARC determined showed sufficient evidence to classify as Group 2B, possibly carcinogenic.

GLASS WOOL INSULATION FIBERS ARE DISTINCT FROM SPECIAL PURPOSE FIBERS

The Draft Background Document distinguishes glass wool and special purpose fibers at various points in the Introduction and Human Exposure sections. Nonetheless, the *Federal Register* notice announcing the availability of the Draft Background Document states that "there is not a clear separation between the physico-chemical properties of glass wool insulation and special purpose fibers." (74 Fed. Reg. at 15,983).

As set forth below, there are very specific distinctions recognized for many years between special purpose fibers and glass wool insulation that both include and go beyond physico-chemical properties.

International and United States Authoritative Bodies Distinguish Glass Wool Insulation and Special Purpose Fibers

The distinction between glass wool insulation and special purpose fibers has long been recognized by multiple authoritative scientific bodies around the world. Over the past twenty-plus years, these authoritative bodies have recognized that insulation glass wools and special purpose fibers can, and should be, distinguished. As summarized below, special purpose fibers are a very small portion of the overall category of glass wool – less than one percent. Because of the unique applications of special purpose fibers, there is minimal consumer exposure, and occupational exposures occur in controlled, non-construction worksites where work practices specifically designed for handling special purpose fibers are employed. A brief summary follows:

World Health Organization ("WHO")

In 1988, the World Health Organization ("WHO") published *Environmental Health Criteria 77: Man-made Mineral Fibres*, which separated MMMFs "into four broad groups: continuous filaments, insulation wools, refractory fibres, and special purpose fibres."[4] WHO identified the following attributes of special purpose fibers that distinguished them from the other three fiber groups: 1) fiber diameter (chemical and physical properties); 2) use or application; 3) raw material; and 4) manufacturing process (flame attenuation).[5]

WHO distinguished special purpose fibers from insulation wools and other fibers because the "majority of special purpose fibres have smaller fibre diameters."[6]

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[4] WHO 1988. *Man-made Mineral Fibres. Environmental Health Criteria.* Vol. 77. Geneva: World Health Organization, pp. 23-24.
[5] WHO 1988, p. 25 and Figure 2, which notes a distinction in manufacturing process.
[6] WHO 1988, pp. 11, 25.

WHO further explained that special purpose fibers "account for only about 1% of world production,"[7] and "are used in special applications, such as high-efficiency filter papers and insulation for aircraft and space vehicles,"[8] whereas glass wool insulation is used mainly for thermal and acoustical building insulation.[9] See WHO Figure 3 for a detailed chart of differentiation by use.[10] In addition, WHO distinguished special purpose fibers as being "made exclusively from glass, whereas insulation wools can also be manufactured from rock or slag."[11]

In distinguishing special purpose fibers from glass wool insulation, WHO relied upon the proceedings of a WHO/IARC conference held in Copenhagen, Denmark in April 1982.[12]

Environment Canada and Health Canada

In 1993, Environment Canada and Health Canada, pursuant to the Canadian Environmental Protection Act, published the *Priority Substances List Assessment Report: Mineral Fibres (Man-Made Vitreous Fibres).* Environment/Health Canada's assessment evaluated four subsets of mineral fibers, which were identified as follows:

- Rock and slag wools, glass wools (excluding glass microfibres);
- Glass microfibres [also referred to as special purpose fibres by the Canadian document];
- Continuous glass filaments;
- Aluminosilicate refractory ceramic fibres.

Throughout the document, Environment/Health Canada consistently distinguishes glass wool insulation from special purpose fibers by specifically excluding glass microfibers from any association with glass wool insulation. Environment/Health Canada also distinguishes these fibers "based upon their use, physical properties, and chemical composition."[13] *See* Table 2, Physical and Chemical Properties of Some Man-made Vitreous Fibres.[14] Environment/Health Canada concur with WHO that special purpose fibres are distinguished from insulation wools in several ways: special purpose fibers have a smaller diameter than glass wool;[15] special purpose fibres are more durable (less bio-soluble) than glass wool;[16] and special purpose fibres have

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[7] WHO 1988, p. 25.
[8] WHO 1988, pp. 25, 34-35 (citations omitted).
[9] WHO 1988, pp. 12, 34-35.
[10] WHO 1988, p. 34.
[11] WHO 1988, p. 25.
[12] WHO/IARC, *Biological effects of man-made mineral fibres, Proceedings of a WHO/IARC Conference, Copenhagen, Denmark, 20-22 April 1982.*
[13] Environment Canada. 1993. *Mineral Fibres (Man-Made Vitreous Fibres), Priority Substances Assessment Report*, p. 5.
[14] Environment Canada 1993, p. 6.
[15] Environment Canada 1993, p. 6.
[16] Environment Canada 1993, p. 7.

unique applications.[17] Finally, Environment/Health Canada explicitly states that "it is fully recognized that there are substantial differences in the physical and chemical properties" of "rock/slag wool, glass wool (excluding glass microfibres), special purpose glass microfibres, continuous glass filament (textile fibres), refractory ceramic fibres."[18]

Most important, Environment/Health Canada placed glass wool insulation and special purpose fibers into distinct and separate classification categories under its carcinogenicity classifications. Glass wool insulation is assigned to Group IV (unlikely to be carcinogenic to humans).[19] Under that same classification system, microfibers or special purpose fibers have been assigned to Group III (possibly carcinogenic to humans).[20]

American Conference of Governmental Industrial Hygienists ("ACGIH")

In the ACGIH series on Threshold Limit Values, the *Documentation of the Threshold Limit Values and Biological Exposure Indices for Synthetic Vitreous Fibers*, offers yet another distinction between glass wool insulation and special purpose fibers. ACGIH identifies the "major categories" and typical uses of SVFs as follows:

- Insulation wools, i.e., glass wool and mineral wools, e.g., rock wool and slag wool;
- Special purpose fibers, e.g., glass fibers used in aerospace and filtration;
- Continuous glass filament, e.g., textiles and reinforcement glass uses;
- Refractory fibers, including refractory ceramic fibers used for high-temperature insulation.[21]

ACGIH succinctly captures these differences in its description of special purpose fibers.[22] ACGIH distinguishes special purpose fibers from glass wool insulation and other SVFs on their physical properties (fiber diameter)[23] and chemical compositions (*See* Table 1),[24] biosolubility,[25] and use.[26]

[17] Environment Canada 1993, p. 9.
[18] Environment Canada 1993, p. 31.
[19] Environment Canada 1993, p. 33.
[20] Environment Canada 1993, p. 34.
[21] ACGIH. 2001. *Documentation of the Threshold Limit Values and Biological Exposure Indices for Synthetic Vitreous Fibers*. American Conference of Governmental Industrial Hygienists. Cincinnati, Ohio, p. 1.
[22] ACGIH 2001, p. 6.
[23] ACGIH 2001, p. 3.
[24] ACGIH 2001, p. 4.
[25] ACGIH 2001, p. 3.
[26] ACGIH 2001, p. 5.

Health Council of the Netherlands

The Dutch Expert Committee on Occupational Standards, a Committee of the Health Council of the Netherlands, issued a report on Man-Made Mineral Fibers ("MMMF") in September 1995.[27] The Expert Committee, composed of European experts on fiber toxicology and industrial hygiene, distinguished six groups of MMMF depending on composition:

1. Continuous filament fiber glass;
2. Glass wool fibers;
3. Rock wool fibers;
4. Slag wool fibers;
5. Refractory ceramic fibers (RCF);
6. Special purpose glass fibers.[28]

International Labour Organisation

The International Labour Organisation ("ILO") is a specialized agency of the United Nations that deals with labor issues. During a ten-day expert panel meeting that included international representatives of labor unions and governments, the ILO updated its Code of Practice for insulation wools in 2000 and distinguished glass wool insulation from special purpose fibers by excluding special purpose fibers from the Code of Practice.[29] This Code was based, in part, on the earlier 1989 ILO health risk assessment for mineral and synthetic fibers. The ILO experts in 1989 categorized the types of mineral and synthetic fibers as follows: 1) Continuous filament glass fibres; 2) Insulation wools (glass wool, rock wool, and slag wool); 3) Refractory fibres; and 4) Special purpose glass fibres. As have most other expert groups, ILO distinguished insulation wools from special purpose fibers based on fiber diameter, use or non-use of binders, and applications or uses.[30]

International Agency for Research on Cancer

The most extensive analysis is that conducted in 2001 by a Working Group of Experts convened by the International Agency for Research on Cancer ("IARC") (Vol. 81), which separated glass wool insulation from special purpose fibers in its grouping system using similar principles and data.[31] IARC based this distinction on durability, chemical composition, applications, health effects data, and classifications by other expert entities.

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[27] Health Council of the Netherlands. *Man Made Mineral Fibers (MMMF): Health based recommended occupational exposure limits*. No. 1995/02 WGD, The Hague. September 8, 1995.
[28] Health Council of the Netherlands 1995, p. 19.
[29] International Labour Organization. *Code of practice on safety in the use of synthetic vitreous fibre insulation wools (glass wool, rock wool, slag wool)*. International Labour Office, Geneva. 2001, p. 3.
[30] International Labour Organization (ILO). *Safety in the use of mineral and synthetic fibres*. Occupational Safety and Health Series. International Labour Office, Geneva. 1990. pp. 9-11.
[31] IARC Monograph 81, p. 44.

IARC recognized the critical importance of durability and biosolubility in fiber toxicity[32] and distinguished glass wool from special purpose fibers based on durability.[33] Thus, special purpose fibers are typically more durable than insulation wools – in some instances, by an order of magnitude both as measured *in vitro* by K_{dis} and *in vivo* by $T_{1/2}$ and $WT_{1/2}$ in well-designed animal inhalation studies. The durability of special purpose fibers is due, in part, to their chemistry and the method of manufacture.

IARC also recognized that special purpose fibers are more highly engineered, make up a very small percentage of the man-made vitreous fiber market, and have a highly specialized application as already noted herein.[34]

Most importantly, IARC recognized that voluminous, high-quality scientific data supported differentiation between glass wool insulation and special purpose fibers. For example, the animal studies database for glass wool insulation is composed of data from well-designed, chronic inhalation studies that found no increase in pulmonary fibrosis, lung, or pleural tumors. These study results led the IARC Working Group to classify the animal evidence for glass wool insulation as "limited." IARC found overall that the evidence of carcinogenicity in humans was "inadequate" for both glass wool insulation and special purpose fibers as it had in its original classification in 1988. In contrast, the SPF database contains positive carcinogenicity data from inhalation and intratracheal instillation studies, which led the Working Group to find the animal evidence "sufficient."

Lastly, IARC recognized and relied upon many of the authoritative bodies cited and quoted above to further support its conclusion that glass wool insulation was markedly different from special purpose fibers and merited a separate and distinct IARC classification. IARC classified glass wool insulation, along with rock and slag wools and continuous filament glass in Group 3, not classifiable as to carcinogenicity to humans. In contrast, refractory ceramic fibers and special purpose fibers remained in Group 2B, possibly carcinogenic to humans, because of their relatively high biopersistence and animal data.

Agency for Toxic Substances and Disease Registry ("ATSDR")

The U.S. Agency for Toxic Substances and Disease Registry ("ATSDR") published its *Toxicological Profile for Synthetic Vitreous Fibers* in September 2004, which is the most recent scientific evaluation of synthetic vitreous fibers conducted by an authoritative body. ATSDR also distinguished glass wool insulation and special purpose fibers. Consistent with IARC, ATSDR classified synthetic vitreous fibers into two broad categories: filaments and wools. *See* Figure 2-1.[35] ATSDR then differentiated both glass wool insulation and special purpose fibers by use, diameter, and manufacturing process: "Glass wool[s] . . . are primarily used in insulating

[32] IARC Monograph 81, pp. 334-335.
[33] IARC Monograph 81, pp. 258-259 – Table 65; pp. 257-263.
[34] IARC Monograph 81, pp. 52, 72, 78.
[35] *Toxicological Profile for Synthetic Vitreous Fibers* (U.S. Department of Health and Human Services, Public Health Services, Agency for Toxic Substances and Disease Registry), September 2004 ("ATSDR 2004"), p. 14.

materials for homes, buildings . . . ." The special purpose fiber group "includes glass fibers produced by flame attenuation for special applications such as high-efficiency air filtration and include special fine-diameter glass fibers."[36]

Again, consistent with IARC, ATSDR distinguished glass wool insulation from special purpose fibers because there was sufficient evidence in animals for the carcinogenicity of special purpose fibers and limited evidence in animals for the carcinogenicity of glass wool insulation.

ATSDR recognized that special purpose fibers require "very specific properties." In other words, special purpose fibers are tailor-made for their specific uses.[37] As ATSDR explains, these "very specific properties" of special purpose fibers are realized through unique physical and chemical properties which ATSDR highlights in Table 4-2[38] and Table 4-3[39] and the accompanying text. Special purpose fibers are distinguished from glass wool insulation by ATSDR's attention to the "very expensive" SPF manufacturing process[40] and the fact that special purpose fibers account for about 1 percent of the synthetic vitreous fibers produced in the United States.[41]

<u>Industry Practice Provides a Clear Delineation of Glass Wool Insulation From Special Purpose Fibers</u>

Like the authoritative groups described above, glass fibers tested in health effects studies have also been distinguished by the industry that produces glass wool insulation and special purpose fibers with reference to durability, typical end uses, chemical composition, fiber diameter, and manufacturing methods.

NAIMA and its member companies have defined for many years, and will in the future define, glass wool insulation, as the authoritative bodies discussed above have recognized, by the following characteristics:

- Glass wool insulation is more biosoluble than special purpose fibers – in some instances, by an order of magnitude or more, both as measured *in vitro* by K_{dis} and by $T_{1/2}$ and $WT_{1/2}$ in well-designed animal inhalation studies. More specifically, any glass fiber manufactured within the range of dissolution rates similar to or more biosoluble than the solubility of MMVF 10 and MMVF 11 will continue to be a glass wool insulation fiber and not a special purpose fiber for listing in the RoC.
- The vast majority of glass wool insulation fibers are manufactured by a rotary process.

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[36] ATSDR 2004, p. 13.
[37] ATSDR 2004, p. 163.
[38] ATSDR 2004, p. 167.
[39] ATSDR 2004, p. 169.
[40] ATSDR 2004, p. 175.
[41] ATSDR 2004, p. 175.

- Glass wool insulation fibers have larger average fiber diameters compared with special purpose fibers, which are distinguished by smaller average diameters. Toxic effects in experimental systems were found in special purpose fibers that were less than 1 μm in diameter.
- Glass wool insulation is used for thermal and acoustical insulation in a variety of settings, including residential, commercial, and industrial buildings. In addition, glass wool insulation fibers are used for pipe insulation, duct board and duct liner.

In addition to these very specific criteria for delineating glass wool insulation fibers, NAIMA has attached a list (Attachment 2) of fibers noted in health effects studies and mentioned in the Draft Background Document and identified these fibers as either glass wool insulation, special purpose fibers, or experimental fibers.

Establishing this clear delineation is relevant from a practical perspective. Substances that are listed in the NTP's RoC as a "reasonably anticipated" carcinogen are required under the OSHA Hazard Communication Standard to print a warning label on product packages and disclose the listing on material safety data sheets ("MSDS"). The industry will use the clear delineation set forth above to make those labeling and disclosure determinations dictated by the Hazard Communication Standard.

BASIS FOR DELISTING

In applying the NTP RoC Listing Criteria to the extensive scientific data, glass wool insulation (respirable size) should be removed from the 12th RoC. This outcome is supported by the IARC Working Group's review and its decision to change the classification of glass wool insulation from Group 2B to Group 3 and by the substantial body of science data supporting that decision. Subsequent to the publication of the IARC Monograph in 2002, the ATSDR analyzed the data in detail and reached conclusions consistent with that of IARC concerning glass wool insulation.

<u>Human Data</u>

NAIMA references with approval the comments submitted on the human data by Dr. Gary Marsh.

In both the original 1988 classification and the IARC re-evaluation contained in Monograph 81 (2002), the human data were determined to be "inadequate." In the years between reviews, the cohort studies were updated, expanded and subjected to more rigorous analyses. IARC summarized the key available cohort data:

> The United States cohort study included 16 plants, extended [since 1988] the follow-up to 1992 and expanded a previous cohort to include women and non-white workers. This study included information on smoking habits and a new assessment of historical workplace exposure to respirable fibres and several

> sources of co-exposures including asbestos, formaldehyde and silica. The European cohort extended the follow-up to 1990 in 13 plants.[42]

Thus, a very large and high quality database is now available on the epidemiology of glass wool manufacturing workers, which IARC summarized shortly after the Working Group completed its review:

> Epidemiologic studies published during the 15 years since the previous IARC Monograph[']s review of these fibres in 1988 provide **no evidence** of increased risks of lung cancer or of mesothelioma (cancer of the lining of the body cavities) from occupational exposures during manufacture of these materials, and inadequate evidence overall of any cancer risk.[43] [Emphasis added.]

These epidemiological data, discussed in detail by Dr. Marsh, IARC, and ATSDR, show no causal relationship between manufacturing workers exposure to glass wool and cancer. This conclusion is consistent with the animal inhalation studies of glass wool insulations (MMVF 10 and MMVF 11), and with biopersistence studies showing these glass wool insulations to be biosoluble, both *in vivo* and *in vitro*.

Nonetheless, IARC in 2002 expressed "some concern" about "risks for workers in industries that use or remove these products (e.g., construction), who may have experienced higher, but perhaps more intermittent, exposure."[44] That question was subsequently answered in a study of fiber glass exposure that compared professional and do-it-yourself installers "estimated working lifetime exposures" to the cumulative lifetime exposures of manufacturing workers studied in the Marsh cohort. The authors concluded that both end user groups "are likely to have substantially lower cumulative lifetime exposures than the manufacturing cohorts."[45] ATSDR summarized this study, which "concluded that due to smaller exposure times, both do it yourself and professional insulation installers had much lower lifetime exposures than workers employed in the manufacturing of fiberglass. . . products."[46] ATSDR further noted that "recent epidemiological studies have concluded that there is no significant increase in respiratory system cancer among the manufacturing cohorts, and therefore, there is even less risk for installers."[47]

Animal Data

NAIMA references with approval the comments on the animal data submitted by Drs. Hesterberg, Donaldson, and Hadley.

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[42] IARC Monograph 81, p. 328.

[43] See IARC Press Release, 24 October 2001, available at http://www.iarc.fr/en/media-centre/pr/2001/pr137.html (last visited May 20, 2009).

[44] IARC Monograph 81, p. 331.

[45] Maxim, L.D., Eastes, W., Hadley, J.G., Carter, C.M., Reynolds, J.W., and Niebo, R., Fiber glass and rock/slag wool exposure of professional and do-it-yourself installers, *Regulatory Toxicology and Pharmacology* 37 (2003) 28-44, p. 28.

[46] ATSDR 2004, p. 193 (citation omitted).

[47] ATSDR 2004, p. 193 (citation omitted).

IARC in 2002 concluded, after extensive review and analysis of newly available data, that the animal evidence for glass wool insulation was "limited." In 1988 IARC did not have the well conducted chronic inhalation studies of rats and hamsters exposed to glass wool insulation, and it did not separate glass wool insulation from special purpose fibers. Therefore, it found "glasswool," the combined body of fibers, to have "sufficient" animal evidence.

The 2002 reclassification to Group 3 by IARC was based upon: (1) well-conducted chronic inhalation studies in two species (rats and hamsters) which showed no evidence of either fibrosis or tumors induced by nose-only exposures to glass wool insulations (MMVF 10 and MMVF 11); and (2) the accumulated body of evidence showing glass wool insulation fibers to be less persistent and to be less durable than other fibers which had shown carcinogenicity in laboratory animals. A growing consensus has concluded that, when all relevant data are considered, well-conducted chronic inhalation studies are more probative of potential human hazard than are injection studies.

First and foremost, the chronic inhalation studies significantly expanded the data available to IARC and were key to reclassification. These studies are well analyzed by IARC[48] and ATSDR,[49] and by Dr. Hesterberg's and Dr. Hadley's comments on the Draft Background Document.

The second major factor leading to IARC's reclassification of the animal evidence to "limited" was the growing consensus as to the relevance of various routes of exposure for hazard assessment. See, for example, Chapter 5 of the National Research Council ("NRC") Report (Attachment 3): "It appears reasonable to conclude that extrapolations from animal toxicity data to humans for MVF can best be made when experimental animals are exposed to fibers via inhalation."[50] Additionally, regarding the issue of intracavitary injection studies, the same NRC report states: "The subcommittee agrees with a WHO scientific panel's conclusion that the intraperitoneal model should not be used for quantitative risk assessment or for comparing relative hazards posed by different fibers (WHO 1992)."[51] In 1996, a workshop report sponsored by EPA in collaboration with NIEHS, NIOSH, and OSHA,[52] similarly concluded: "After extensive discussion and debate of the workshop issues, the general consensus of the expert panel is that chronic inhalation studies of fibers in the rat are the most appropriate tests for predicting inhalation hazard and risk of fibers to humans."[53]

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[48] IARC Monograph 81, pp. 181-191, 332.
[49] ATSDR 2004, p. 96-107.
[50] National Research Council, *Review of the U.S. Navy's Exposure Standard for Manufactured Vitreous Fibers* (2000), p. 39.
[51] *Ibid.*
[52] Vu, V., Barrett, J.C., Roycroft, J., Schuman, L., Dankovic, D., Baron, P., Martonen, T., Pepelko, W., and Lai, D., Workshop Report, Chronic Inhalation Toxicity and Carcinogenicity Testing of Respirable Fibrous Particles, *Regulatory Toxicology and Pharmacology* 24 (1996) 202-212.
[53] *Ibid.*, p. 202.

The now well-established role of fiber biopersistence in the potential biological activity of fibers also played an important role in the IARC reevaluation of the animal data: "It is important to appreciate the degree to which biopersistence plays a role in the different studies and end-points under review, as this property of fibres is thought to be critical in determining chronic toxicity and carcinogenic outcome in humans and in experimental animal systems."[54]

GENERAL AND SPECIFIC COMMENTS ON DRAFT BACKGROUND DOCUMENT

The following provides general comments applicable, in some instances, to the entire Draft Background Document, and specific comments on the Human Exposure and Other Relevant Data sections, along with line-by-line corrections and suggested changes for the Draft Background Document.

In 2000, the National Academy of Sciences conducted an extensive review of the scientific data on "Manufactured Vitreous Fibers." This review concluded that it found "no significant association between fiber exposure and lung cancer or nonmalignant respiratory disease in the MVF [man-made vitreous fiber] manufacturing environment."[55] The Draft Background Document makes no mention of this review.

The Draft Background Document has no summary of IARC's basis for finding inadequate evidence of carcinogenicity in the human data in Chapter 3 – Human Cancer Studies. Chapter 4 – Studies of Cancer in Experimental Animals has one short paragraph (4.6) to describe both the 1988 and 2002 IARC Monographs. Given that IARC is the basis for both Petitions before NTP, an analysis of IARC's review of the extensive data merits a more fulsome discussion in the Draft Background Document.

The Draft Background Document (at p. 4) also cites a fiber classification system created in an article by Moore, *et al.* This classification system is misplaced in a background document on insulation glass wool as it is generic to the broad class of synthetic vitreous fibers, and is a proposed system for screening fibers for potential health effects. It concludes that durable, respirable fibers are the most potentially hazardous, which is well known in the fiber science community. The system has not been adopted by any authoritative body.

<u>Introduction</u>

Section 1:3. In discussing fiber classification systems, both the European and German classification systems seem, as described in the Draft Background Document, to consider glass wool insulation as carcinogenic. The Draft Background Document should state that application of the testing criteria set forth in these classification systems to glass wool insulation fibers has been applied to exempt glass wool insulation fibers from classification as carcinogens. For example, the two glass wool insulations (MMVF 10 and MMVF 11) studied in the chronic

[54] IARC Monograph 81, p. 289.

[55] National Research Council, *Review of the U.S. Navy's Exposure Standard for Manufactured Vitreous Fibers* (2000), p. 49.

inhalation studies both meet the EU criteria for exemption as neither was found to produce either fibrosis or tumors via inhalation. As for the German classification system, it does not recognize inhalation as a route of exposure that can exonerate a fiber, though it does accept an intratracheal instillation biopersistence test, which many glass wool insulation fibers have passed and are sold in Germany without any cancer warning label.

Human Exposure

In Section 2.0, the Draft Background Document states that the general population is exposed to insulation glass wool fibers. While this is true, the exposures are very low.[56] Many studies which evaluated exposures in buildings, including homes, schools, office buildings, and commercial buildings, found very low levels of synthetic vitreous fibers ("SVFs"), in many cases below the level of detection. Average exposures in the studies range from 10^{-3} to 10^{-5} f/cc, which is several orders of magnitude lower than the recommended occupational exposure limits of 1 f/cc. In most of the studies, the maximum exposure measurement is well below 10^{-3} f/cc.[57]

These very low exposures to the general population were summarized by the ATSDR's Toxicological Profile on Synthetic Vitreous Fibers:

- "The exposure of the general population (non-occupational exposure) to synthetic vitreous fibers in both indoor and outdoor air is low."[58]
- "Very low levels of synthetic vitreous fibers can be found in virtually all homes, buildings, and outside air, but there is little concern regarding these low levels. As long as the materials are not physically disturbed or breaking down, the levels of synthetic vitreous fibers in the air should be very low."[59]

Similarly, the Draft Background Document references exposure to fibers near manufacturing facilities. Using an EPA-approved protocol, 41 U.S. fiber glass manufacturing facilities were monitored for ambient exposures near the facilities. The results of this near-source testing demonstrate that the respirable mineral fiber emissions are extremely low.[60]

Section 2.3.2, second paragraph. The Draft Background Document cites to Maxim, *et al.*, for the number of insulation installers exposed in the United States. It should also indicate that the Maxim paper was a quantitative analysis of exposures in installers versus manufacturing workers. As this is a long-standing question in the fiber community, the Draft Background

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[56] Schneider, T., Burdett, G., Martinon, L., Brachard, P., Guillemin, M., Teichert, U., Olson, E., and Draeger, U., Ubiquitous Fibre Exposure in Europe: A Pilot Study (Halden Strobe: Hewea Druck Ges. Mott, 1995).
[57] In 23 studies, MMVF exposures were evaluated in a wide variety of consumer exposure scenarios (Attachment 4).
[58] ATSDR 2004, p. 188.
[59] ATSDR 2004, p. 9.
[60] Switala, E.D., Harlan, R.C., Schlaudecker, D.G., Bender, J.R., Measurement of respirable glass and total fiber concentrations in the ambient air around a fiberglass wool manufacturing facility and a rural area, *Regulatory Toxicology and Pharmacology* 20 (3 Pt 2) (1994) S76-88.

Document should provide the results of the Maxim paper, which reported much less cumulative exposure for installers than for manufacturing workers.

The Draft Background Document spends an unwarranted amount of space on exposure studies dating back to the 1960s and 1970s. More recent exposure data merit equal consideration as demonstrated by both IARC and ATSDR's full evaluation of all human exposure data.[61] The Draft Background Document characterizes the Health and Safety Partnership Program ("HSPP") database as containing "data collected or commissioned by NAIMA," but fails to recognize that it also contains extensive data from NIOSH sampling programs and other government-sponsored data collection efforts. In addition, the HSPP database is maintained by a third-party independent consultant at Arizona State University, who serves as the Database Manager.[62] The quality assurance and quality control measures are described in two different peer-reviewed articles.[63]

The HSPP exposure database currently contains over 14,000 data points. Exposure data are classified by job descriptions for glass manufacturing, installation, and fabrication. Average exposure levels are reported by product type and job description. The true test of the authenticity and legitimacy of the HSPP data is that the exposures reported and the range of those exposures are consistent with the exposure data published in the non-industry exposure articles cited in the Draft Background Document itself. Specifically, NIOSH evaluated individual job sites for synthetic vitreous fiber exposures in 1992 and 1993 and found "very low exposure levels generally below 0.1 f/cc, although with relatively small sample sizes. These exposure data were presented in agency reports,[64] but have not been published in a peer-reviewed journal."[65] A number of published studies have reported occupational exposure levels in manufacturing or installation operation to be generally below 1 f/cc.[66]

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[61] IARC Monograph 81, pp. 80-126; ATSDR 2004, pp. 188-202.

[62] Marchant, G.E., et al., A Synthetic Vitreous Fiber (SVF) Occupational Exposure Database: Implementing the SVF Health and Safety Partnership Program, *Applied Occupational and Environment Hygiene*, 17(4): 276-285, 2002, p. 279.

[63] Marchant, G.E.. et al., A Synthetic Vitreous Fiber (SVF) Occupational Exposure Database: Implementing the SVF Health and Safety Partnership Program, *Applied Occupational and Environment Hygiene*, 17(4): 276-285, 2002. Marchant, Gary; Bullock, Christopher; Carter, Charles; Connelly, Robert; Crane, Angus; Fayerweather, William; Johnson, Kathleen; and Reynolds, Janis (2009), Applications and Findings of an Occupational Exposure Database for Synthetic Vitreous Fibers, *Journal of Occupational and Environmental Hygiene*, 6:3, 143-150.

[64] National Institute of Occupational Safety and Health: Health Hazard Evaluation Report (HETA 91-003-2232). Scoot Molders, Inc., Kent, OH (July 1992). National Institute of Occupational Safety and Health: Health Hazard Evaluation Report (HETA 91-120-2286). U.S. Department of Veterans Affairs, Austin, TX (Feb. 1993).

[65] Marchant, G.E., et al., A Synthetic Vitreous Fiber (SVF) Occupational Exposure Database: Implementing the SVF Health and Safety Partnership Program, *Applied Occupational and Environment Hygiene*, 17(4): 276-285, 2002, p. 277.

[66] For example, Lees, P.S.J., Breysse, P.M., McArthur, B.R., et al., End User Exposures to Man-Made Vitreous Fibers: I. Installation of Residential Insulation Products, *Applied Occupational and Environment Hygiene*, 8:1022-1030 (1993).

The Draft Background Document discusses the exposure to SVFs after the World Trade Center disaster. While the relevance of this discussion is unclear in the Draft Background Document, it is important to place this unique exposure scenario in proper perspective.

The thousands of tons of building debris released into the atmosphere after the collapse of the World Trade Center on September 11, 2001, consisted of more than 2,500 contaminants. The American Chemical Society analyzed 25 residences and 9 building interior common areas in Upper Manhattan and found that SVFs were "at very low concentrations" in some locations. Wipe tests in residential areas showed the presence of SVFs in 11 of 99 samples; wipe tests in common areas showed the presence of SVFs in 3 of 42 samples.[67] The "World Trade Center Indoor Air Assessment" was a report prepared by various government agencies on fiber glass exposures.[68] It reported, among other findings, that the presence of fibrous glass in settled dust does not indicate a potential for exposure. It further stated that "[a]ir samples collected in areas with fibrous glass in settled dust indicate no fiber levels of immediate concern."[69]

<u>Studies of Cancer In Experimental Animals</u>

The Draft Background Document should distinguish between glass wool insulation and special purpose fibers throughout the discussion on studies of cancer in experimental animals. Though Table 3-1 gives an accurate listing of the fibers, no indication of which fibers are glass wool insulation or special purpose fibers is made in the subsequent tables. Given the importance of the separation of glass wool insulation from special purpose fibers, a single set of tables labeled ". . . studies of glass wool" should be created. The tables should be redone with a Part 1 "Studies with insulation wools" and Part 2 "Studies with special purpose fibers." This approach will allow reviewers to judge the adequacy of the data sets.

- Table 4-2 – One glass wool insulation, and one special purpose fiber (475).
- Table 4-3 – Of the 18 fibers, 12 were glass wool insulation. None of the studies were positive.
- Table 4-4 – MMVF 10 and MMVF 11 are size separated fractions of glass wool insulation. 104/475 and 104/e are special purpose fibers.
- Table 4-5 – MMVF 10 is a size separated fraction of a glass wool insulation. MMVF 33 is a special purpose fiber.
- Table 4-6 – Title should change "glass wool fibers" to "special purpose fibers."
- Table 4-7 – Glass wool insulation should be identified so the reader would understand that positive results were seen only from clearly defined special purpose fibers (JM 100 series).

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[67] Tang, K.M., Nace, C.G., Lynes, C.L., Maddaloni, M.A., LaPosta, D., and Callahan, K.C., Characterization of Background Concentrations in Upper Manhattan, New York Apartments for Select Contaminants Identified in World Trade Center Dust, *Environmental Science & Technology*, 2004, 38 (24), pp. 6482-6490.

[68] *World Trade Center Indoor Air Assessment: Selecting Contaminants of Potential Concern and Setting Health-Based Benchmarks* (www.tera.org/peer/WTC/COPC%20-%20Final%20-%2009-12-02.pdf) (last visited May 20, 2009).

[69] *Ibid.*, p. 7.

- Figure 4-1 – Title should add "special purpose" for precision.
- Table 4-9 – Only two glass wool insulations in the entire 5-page, 12-study table, MMVF 10 and MMVF 11, were listed. The Table should be split into Table A and Table B to clearly show the fibers tested and to conform to the two separate nominations being considered.

Other Relevant Data

As above, the reader cannot distinguish glass wool insulation data from special purpose fiber data. Grouping all results together is not as helpful as separate discussions of glass wool insulation and special purpose fibers would be. For example, multiple pages of text are devoted to the studies of Pott, but only one glass wool insulation study (MMVF 11) was included. All other data are for special purpose fibers. This should be indicated. Consider the following information on Tables 5-1A to 5-1I:

- Table 5-1A – Indicate which are glass wool insulations.
- Table 5-1B – No glass wool insulation tested.
- Table 5-1C – No glass wool insulation tested.
- Table 5-1D – No glass wool insulation tested.
- Table 5-1E – No glass wool insulation tested.
- Table 5-1F – Only one glass wool insulation tested (MMVF 11).
- Table 5-1G – No commercial insulation wools tested.
- Table 5-1H – Only one glass wool insulation tested (MMVF 10).
- Table 5-1I – No commercial insulation wools tested.

Therefore, the Draft Background Document should note that in 16 pages of detailed data, only two glass wool insulation studies are presented – one with MMVF 10 and one with MMVF 11. Adding "glass wool insulation" and "special purpose fiber" in the "Comment" box would be more informative.

- Table 5-2 – Should indicate that MMVF 32 and MMVF 33 are special purpose fibers.

Specific Line-By-Line Comments

- Page xiii, line 4 – The reference to aerodynamic diameters should read < 1-2 μm.
- Page xiii, lines 11-13 – It should be noted that overload is not restricted to low toxicity fibers.
- Page xiv, line 14 – The Draft Background Document states that "longer fibers induced greater toxicity" but it should be added that the greater toxicity is in contrast to shorter fibers.
- Page 4 – Delete Figure 1-2 (see discussion above about Moore article).
- Page 6, Table 1-3 – Title should read "Codes for Manville Special Purpose Fibers."

- Page 17, line 29 – "heat" insulation would be more accurately characterized as "thermal" insulation.
- Page 37, lines 19-23 – The Draft Background Document should note that homeowners doing renovations would have low cumulative exposures as their frequency and duration of exposures is significantly lower.
- Page 118, line 3 – Change "fiber number" to fibers/cc.
- Page 118, lines 5-7 – Change "fiber number" to fibers/cc.
- Page 126, lines 12-15 – It is not clear whether the authors are talking about the glass or asbestos exposed rats, or both.
- Page 126, line 19 – The tumors seen in the crocidolite exposed rats should be mentioned.
- Page 146, line 20 – Does "half-life" refer to lung half-life? The Draft Background Document should be specific.
- Page 147, line 10 – Does "half-life" refer to lung half-life? The Draft Background Document should be specific.
- Page 148, line 1 – K_{dis} refers to biosolubility, not durability.
- Pages 150-154, Table 4-9 – The Table should note the length of the studies.
- Page 174, Section 5.2.2 Dissolution – The studies by Walter Eastes included in the IARC Monograph should be summarized or referenced here.
- Page 176, lines 14-28 – The specific clearance rates for the glass fibers should be added.
- Page 218, line 17 – There is no explanation for why the hamster and rat are different.

CONCLUSION

The NTP has before it two separate nominations related to glass wool fibers. NAIMA's Petition to Delist "glass wool (respirable size)," which has been the focus of these comments, asks the NTP to remove the listing for glass wool from the RoC. NAIMA based its Petition for Delisting on the extensive published scientific research and the conclusions reached by both IARC in 2001 and the National Academy of Sciences in 2000. Specifically, IARC's decision to change the classification of glass wool insulation from Group 2B to Group 3 was supported by IARC's conclusion that the human data remained "inadequate," but the animal data for glass wool insulation was no longer "sufficient," classifying it as "limited." Subsequent to the published conclusions by IARC and NAS, ATSDR reached similar conclusions in 2004. NAIMA relies upon the ATSDR throughout these comments as an additional support for its Petition for Delisting. The extensive published research demonstrates, as confirmed by IARC, NAS and ATSDR, that "glass wool (respirable size)" does not meet either the criteria for human or animal evidence that are required for listing in the RoC.

In addition, mechanistic considerations on the role of biopersistence support the conclusion that the animal data derived from intracavitary injection studies are no longer considered adequate to provide "sufficient evidence of animal carcinogenicity." Therefore, NTP has a solid foundation upon which to delist glass wool (respirable size) from the RoC. As to the NIEHS nomination to list special purpose fibers, NAIMA has restricted it comments to delisting "glass wool (respirable size)" and as such glass wool insulation. Any discussion related to special purpose fibers in these comments is to show that special purpose fibers and glass wool insulation have been regularly differentiated by numerous U.S. and international bodies. Equally important, these comments describe a clear delineation between these two fiber types based on manufacturing method, end uses, chemical composition, fiber diameter, and physical properties, especially their biosolubility.

Sincerely,

[Redacted]

Kenneth D. Mentzer
President and CEO

Attachments

ATTACHMENT 1

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Institute of
Environmental Health Sciences
P.O. Box 12233
Research Triangle Park, N.C. 27709
Website: www.niehs.nih.gov

November 9, 2005

Angus E. Crane
Vice President, General Counsel
North American Insulation Manufacturers Association ("NAIMA")
44 Canal Ctr Plaza
Alexandria, VA 22314

Dear Mr. Crane,

Pursuant to November 4, 2005 letter I would like to clarify what action the National Toxicology Program (NTP) will take for the review of certain glass wool fibers.

First I would emphasize that based on the initial NAIMA nomination for delisting glass wool (respirable size) from the Report on Carcinogens (RoC), it is the NTP's intention to review the current listing of glass wool (respirable size) to determine if this listing should remain in or be removed from the RoC. This review will be part of the consideration of the certain glass wool fibers nomination. As indicated in the October 18, 2005 Federal Register (70 Fed. Reg. 60,552) the basis of the certain glass wool fibers nomination is the recent International Agency for Research on Cancer (IARC) finding of limited evidence of carcinogenicity in animals for insulation glass wool and its evaluation as an IARC Group 3 (not classifiable as to its carcinogenicity to humans), and the finding of sufficient evidence of carcinogenicity in animals for special-purpose glass fibers (IARC Monograph Vol. 81, 2002).

I hope this clarifies what action the NTP intends for the certain glass wool fibers nomination and apologize for any confusion the latest Federal Register notice may have caused. Please contact me if you have any additional questions.

Sincerely,

[Redacted]

C.W. Jameson, Ph.D.
Head, Report on Carcinogens
National Toxicology Program

cc:
Dr. J. Bucher

ATTACHMENT 2

GLASS WOOL INSULATION FIBERS IDENTIFIED IN DRAFT BACKGROUND DOCUMENT FOR GLASS WOOL FIBERS

Fiber	Description
Manville 901	Manville 901 is the Johns Manville glass wool insulation fiber also known as MMVF10 in many studies. Johns Manville 901 fibers are made by the HERM rotary process. Manville 901 is NOT a special purpose fiber.
Owens-Corning general building insulation fibers	Owens Corning general building insulation fibers are NOT special purpose fibers.
German glass wool	German glass wool is NOT a special purpose fiber.
Insulsafe II CertainTeed B Glass Wool	Insulsafe II and CertainTeed B Glass Wool are NOT special purpose fibers.
Glass wool	Almost all commercial glass wool insulation compositions produced in the last 50 years or so are within the same composition family based on SiO_2, alkaline earth oxides (CaO and MgO), and alkali metal oxides (Na_2O and K_2O) with lesser amounts of B_2O_3, Al_2O_3 and sometimes other additives necessary for manufacturing or to achieve the required product performance. This family of glass wools are glass wool insulation fibers.
Glass cotton	Historically, the terms "glass wool" and "glass cotton" have been used interchangeably. There is no compositional differentiation. In fact, in China, the terms "glass wool" and "glass cotton" are still used interchangeably for the same product. See http://www.made-in-china.com/showroom/tsingtaolisa/product-detailXbCQcWtEvmUP/China-Glass-Cotton-Glass-Wool.html
Manville building insulation	"Manville building insulation" should mean Johns Manville 901-MMVF10. Manville 901 and Manville building insulation are NOT special purpose fibers.
CertainTeed B	This is a glass wool insulation fiber product similar to MMVF 11.
"Stanton fibers"	It appears the fibers are identified in the 1988 IARC Monograph number 43 on page 104. There is also a discussion at page 588 of the Stanton article that offers some insight into the composition of the fibers but does not give the specific formulations of those glasses. It is of interest that all the samples were administered on a fibrous glass wool insulation pledget (IARC 43 at 104). Thus the control was actually fiber glass insulation wool.
MMVF 10	Glass wool insulation fibers.
MMVF 10A	Glass wool insulation fibers.
MMVF 11	Glass wool insulation fibers.

SPECIAL PURPOSE FIBERS IDENTIFIED IN DRAFT BACKGROUND DOCUMENT FOR GLASS WOOL FIBERS

Fiber	Description
JM 475	"JM 475" denotes a particular glass fiber chemistry made by Johns Manville. Such a general reference could include various average fiber diameters. Several other U.S. manufacturers also make a 475 chemistry fiber with similar diameters (as well as chemistries similar to Johns Manville 253 and 753), including: Lausche; Evanite; and UPF-ConGlass. In addition, 475 chemistry fibers are made in China and imported into the U.S. "JM 475" is a special purpose fiber.
JM 100	For Johns Manville fibers, a two- or three-digit number called a "Code" was (and today still is) used to denote an average fiber diameter. There are two different Code groupings: 100-series and 200-series. The 100-series grouping includes Codes 90, 100, 102, 104, 106, 108A, 108B, 110, 110X, 112, 112X and CX. The 200-series grouping contains the Codes 206, 210X, 212X and CX. Within each grouping, the higher the Code number, the greater the average diameter of the fiber. Any of these Codes with an X in their designation indicates they are made on a rotary process. Any Code without the X in the name is made by the flame attenuation process. The current Johns Manville Micro-Fiber data sheet at http://www.jm.com/engineered_products/filtration/products/microfiber.pdf lists the most commonly purchased products. These average diameter Codes were used with several different fiber chemistries, including 475, 253, 753, Q (for quartz), and E-glass; however, 475 was the most frequent chemistry. The chemistry of any 100-series product is 475 glass unless a suffix is added indicating that a different chemistry has been used (e.g., 106-253). The chemistry of all 200-series products is 253 chemistry. The CX Code must have a suffix indicating which glass chemistry has been used (e.g., CX-475). Johns Manville no longer makes fine diameter fiber with 753 or E-glass chemistries. Thus, "JM 100" means a 475 chemistry fiber of a certain average diameter made by the flame attenuation process and should be synonymous with "JM 100/475." JM 100 is a special purpose fiber.
Manville 100 microfiber	"Manville 100 microfiber" would denote a special purpose fiber of a certain average diameter made by the flame attenuation process. The chemistry of such a fiber was 475 unless a suffix was added to indicate the use of a different glass chemistry (e.g., 100-253).
JM 104	"JM 104" means a fiber of a certain average diameter greater than JM 100 and made by the flame attenuation process. The chemistry of such a fiber was 475 unless a suffix was added to indicate the use of a different glass chemistry (e.g., 104-253 or 104/753). This is a special purpose fiber.
Manville code 108A	"Manville Code 108A" means a fiber of a certain average diameter greater than JM 100 and made by the flame attenuation process. The chemistry of such a fiber was 475 unless a suffix was added to indicate the use of a different glass chemistry (e.g., 104-253 or 104/253). The "A" is just an additional Code designation denoting that the average diameter falls within a narrower range than the original Code 108 product. This is a special purpose fiber.
JM 108B	"JM 108B" means a fiber of a certain average diameter greater than JM 100 and made by the flame attenuation process. The chemistry of such a fiber was 475 unless a suffix was added to indicate the use of a different glass chemistry (e.g., 104-253 or 104/253). The "B" is just an additional Code designation denoting that the average diameter falls within a narrower range than the original Code 108. And Code 108A has a slightly finer average diameter than the Code 108B. This is a special purpose fiber.

JM 110	"JM 110" means a fiber of a certain average diameter greater than JM 100 and made by the flame attenuation process. The chemistry of such a fiber was 475 unless a suffix was added to indicate the use of a different glass chemistry (e.g., 104-253 or 104/253). This is a special purpose fiber.
JM 112	"JM 112" means a fiber of a certain average diameter greater than JM 100 and made by the flame attenuation process. The chemistry of such a fiber was 475 unless a suffix was added to indicate the use of a different glass chemistry (e.g., 104-253 or 104/253). This is a special purpose fiber.
JM C102	"JM C102" means a fiber of a certain average diameter greater than JM 100 and made by the flame attenuation process. The chemistry of such a fiber was most likely 475 but also could have been 253. The "C" denotes a fiber made in the 1960s and 1970s for an interlay for filter tubes. This is a special purpose fiber.
JM C104	"JM C104" means a fiber of a certain average diameter greater than JM 100 and made by the flame attenuation process. The chemistry of such a fiber was most likely 475 but also could have been 253. The "C" denotes a fiber made in the 1960s and 1970s for an interlay for filter tubes. This is a special purpose fiber.
JM 104E & 104E	"JM 104E" and "104E" are likely meant to refer to the same fiber, viz., a fiber of a certain average diameter of E-glass chemistry and made by the flame attenuation process. However, 104E without the JM designation could refer to a fiber made by a manufacturer other than Johns Manville. Both JM 104E glass fibers and 104E are special purpose fibers.
E glass & E Glass Microfiber	"E-glass" refers to a certain chemistry that is well defined by ASTM-D578-05. "E glass microfiber" refers to an E-glass special purpose fiber with a typical average diameter of six microns or less. E glass microfiber is a special purpose fiber. This is in contrast to E-glass reinforcement fibers, which have typical average diameters of 7 to 15 microns. E-glass reinforcement fibers are neither special purpose fibers nor glass wool insulation fibers but instead are continuous filaments.
Owens-Corning AAA-10 glass fibers	These are special purpose fibers.
Pyrex wool filtering fiber	Pyrex is a defined composition of a glass. According to the National Institute of Standards and Technology, borosilicate Pyrex is composed of (in weight %): 4% boron, 54% oxygen, 3% sodium, 1% aluminum, 38% silicon, and less than 1% potassium. According to glass supplier Pulles and Hannique, borosilicate Pyrex is made of Corning 7740 glass (<u>this is the Corning Glass Company not Owens Corning</u>), and is equivalent in formulation to Schott Glass 8830 glass sold under the "Duran" brand name. The composition of both Corning 7740 and Schott 8830 is given as 80.6% SiO_2, 12.6% B_2O_3, 4.2% Na_2O, 2.2%Al_2O_3, 0.04% Fe_2O_3, 0.1% CaO, 0.05% MgO, and 0.1% Cl. This is a special purpose fiber.
Tempstran Code 100/475	"Tempstran" is a discontinued Johns Manville trade name for a family of flame attenuated borosilicate glass fibers developed for the paper industry. Tempstran fibers were available in 475, 753, Q (for quartz), and E-glass chemistries. (The current Johns Manville brand name is Micro-Strand.) Thus, Tempstran 100/475 and JM100/475 were likely the same. JM 100 should be 475 chemistry but could also be other chemistries. It was a special purpose fiber.
MMVF 33	JM 475 fibers are also designated MMVF 33 in many studies. MMVF 33 is a special purpose fiber.

ATTACHMENT 2

EXPERIMENTAL FIBERS IDENTIFIED IN DRAFT BACKGROUND DOCUMENT FOR GLASS WOOL FIBERS

Fiber	Description
B-1 and B-2 (glass type 3101), and B-3 (glass type 3102) experimental fibers	The composition of these experimental fibers is given in Table 1 as set forth in F. Pott, M. Roller, R.M. Rippe, P.G. Germann, and B. Bellmann, "Tumours By The Intraperitoneal And Intrapleural Routes And Their Significance For The Classification Of Mineral Fibres," *Mechanisms in Fibre Carcinogenisis*, Edited by R.C. Brown *et al.*, Plenum Press, New York, 1991. Table 1 from the Pott article is attached hereto. These fibers were never commercially produced.
B-01 and B-09 (specific fiber referred to as B-01-0.9, B-09-0.6, and B-09-2.0)	The composition of these experimental fibers is given in Table 1 as set forth in F. Pott, M. Roller, R.M. Rippe, P.G. Germann, and B. Bellmann, "Tumours By The Intraperitoneal And Intrapleural Routes And Their Significance For The Classification Of Mineral Fibres," *Mechanisms in Fibre Carcinogenisis*, Edited by R.C. Brown *et al.*, Plenum Press, New York, 1991. Table 1 from the Pott article is attached hereto. These fibers were never commercially produced.

ATTACHMENT 3

Review of the U.S. Navy's Exposure Standard for Manufactured Vitreous Fibers

NATIONAL RESEARCH COUNCIL

5

TOXICOLOGICAL STUDIES

IN support of its selection of an occupational exposure standard of 2 fibers/cm^3 for manufactured vitreous fibers (MVF), the Navy reviewed much of the available toxicological literature published before 1997. It presents this information as taken from in vitro studies, epidemiological studies (discussed in the next chapter), and animal toxicity studies. The animal toxicity studies are grouped by fiber type and route of administration. The published literature cited by the Navy are current through 1997. However, some relevant toxicological material published since the Navy's 1997 report might inform the Navy's selection of an occupational exposure limit.

The Navy correctly notes that inhalation studies have yielded the most relevant data, as they were conducted using the route of administration that most closely mimics expected human exposures. It also acknowledges the controversy with regard to some aspects of animal toxicity testing of MVF, including the validity of intrapleural and intraperitoneal administration. The subcommittee agrees with the Navy that the route of administration is one of the most controversial aspects of toxicity studies of MVF. Although the Navy does mention some of the controversy and limitations of the toxicity studies it reviewed, it does not elaborate on the limitations of the noninhalation studies. In general, an assessment of the toxic effects of inhaled fibers requires consideration of both the animal model and the fibers' characteristics, including its dimensions, durability, biopersistence, and surface characteristics.

Inhalation, intratracheal instillation, and intracavitary injection studies in animals have been used for estimating the biopersistence and hence potential toxicity and carcinogenicity of inhaled MVF in humans. Each kind of study has advantages and limitations, as discussed in McClellan et al. (1992) and McConnell (1995) and briefly presented below.

INHALATION STUDIES

Experimental data are essential for providing basic information on the physiological and pathophysiological pulmonary responses to inhaled particles. Because various rodent species respond differently to selected inhaled materials, it is essential to consider numerous factors—such as anatomy and deposition patterns, physiology and macrophage clearance efficiency, biochemistry and inflammation and fibrogenic potential—when extrapolating the results of animal inhalation studies to humans. Therefore, knowledge of morphological and functional pulmonary characteristics is essential for full understanding of structure-function relationships among species but it is also necessary if one is to develop accurate risk estimates with regard to the toxicity of inhaled particles in exposed humans.

Several rodent species are commonly used in particle and fiber inhalation-toxicity studies designed to simulate human exposures and to evaluate lung responses to inhaled dusts. But experimental animals and humans differ with respect to lung anatomy and physiology and these differences influence particle deposition and corresponding lung-clearance responses. For example, humans have relatively symmetrical dichotomous airway branching that favors concentrated deposition on branch points, or bifurcations; rodents have highly asymmetric, monopodal branching that theoretically should reduce the tendency for concentrated deposition. Distal airways are fundamentally different between humans and rodents: humans have several generations of nonrespiratory bronchioles and three generations of respiratory bronchioles and alveolar ducts; guinea pigs and hamsters have poorly develop respiratory bronchioles, and mice and rats generally lack them. Humans and rodents have different pleural tissue anatomy. And rodents are obligate nasal breathers, whereas humans can favor oral breathing while speaking or during strenuous activity, thus permitting enhanced particle penetration to the lungs.

Several studies have used rats and hamsters as the primary species for assessing the chronic effects of inhaled fibers (Mast et al. 1994; Mast et al. 1995a; McConnell et al. 1999). Some have demonstrated clear interspecies differences in lung-tumor and mesothelioma responses to inhaled synthetic fibers. Rats appear to be more likely to develop lung tumors after exposure to refractory ceramic fibers (RCF) than hamsters, which have greater sensitivity for developing mesotheliomas (Mast et al. 1994; McConnell et al. 1994). Hamsters appear to be resistant to the development of lung tumors after chronic exposure but appear to be extremely sensitive to mesothelioma induction after exposure to selected fiber types. Because few chronic fiber inhalation studies of appropriate reference materials have been conducted in hamsters, it is difficult to determine whether the hamster is a relevant model for humans. Similarly, interpretations of lung-tumor response in chronically exposed mice are difficult because of the high incidence of spontaneous lung tumors.

Nevertheless, mammalian inhalation tests have some obvious advantages over other tests. The route of exposure is similar to that in humans, and the exposure to fibrous materials is directed to the intact pulmonary system, including all natural defense mechanisms. In rats, the incidences of fibrosis, lung cancer, and mesothelioma after exposure to asbestos are comparable with those in humans (Warheit and Hartsky 1994).

Disadvantages of animal inhalation studies include species differences in respiratory anatomy and function noted above, and species-specific pathological responses in control and treated animals (especially, in the latter, to exposures that result in overloading of the animals' capacity to clear deposited particles and fibers). Animal inhalation studies for fiber toxicity screening tend to be time-consuming, are expensive, and cannot necessarily elucidate the details of cellular and molecular events.

Despite the limitations, a panel of the World Health Organization (WHO) has concluded that inhalation studies constitute the best available laboratory model for assessing the human health risks posed by exposures to fibers (McClellan et al. 1992; WHO 1992).

Subchronic and chronic inhalation tests are typically used to study health effects and dose-response relationships. Recently, short-term inhalation studies (about 1-day to 2-weeks) with extended followup have been used to study biopersistence, cellular reactions, proliferative reactions, and repair and clearance mechanisms. For studying biopersistence of MVF in this fashion, methods for digesting the lung must be validated. Some techniques for validating the methods, such as low-temperature ashing and digestion with strong acids or bases, have limitations. For instance, low-temperature ashing can make the fibers brittle or artificially break them, and digestion with strong acids or bases can destroy retained fibers or alter their composition. Therefore, alternative digestion techniques that preserve each fiber type need to be developed.

That physical characteristics of the fibers, such as fiber dimensions, play an important role in the pathogenesis of fiber-associated lung disease was demonstrated clearly by Davis et al. (1986), who compared the effects of short and long amosite asbestos fibers at equivalent mass concentrations. Rats were exposed for 1 year by inhalation to aerosols of specially prepared short amosite asbestos fibers (shorter than 5 μm) or long amosite asbestos fibers (longer than 20 μm); the two preparations were derived from the same source and at equivalent gravimetric concentrations. As a result, rats were exposed to greater numbers of short fibers than long fibers. After exposure, no significant histopathological effects were observed in the lungs of rats exposed to the short fibers, but one-third of the rats exposed to the long fibers developed lung tumors. Nearly all the rats exposed to the long fibers also developed diffuse pulmonary fibrosis.

Inhalation toxicity studies in rodents must be extrapolated to humans cautiously. Rats or other rodent species generally are experimentally exposed to high concentrations of preparations of long fibers by enriching the aerosol with the fibers. But, such exposures might not adequately simulate occupational or environmental exposures to lower fiber concentrations or to mixtures of fibers of varied lengths; rather, they are designed to represent a potential worst-case scenario.

INTRATRACHEAL INSTILLATION

Studies that use intratracheal instillation as a route of rodent exposure to fibers are generally regarded as easier and less expensive than inhalation studies. Bolus administration often leads to uneven distribution of fiber-shaped particles throughout the lung and localized overloading (ECETOC 1996). Nevertheless, these types of studies might have value for the initial screening of fibrous compounds. A European Commission (EC) directive for classification and labeling of synthetic mineral fibers (Commission Directive 97/96/EC of December 5, 1997) allows for the use of either the short-term inhalation biopersistence assay or the intratracheal-instillation biopersistence assay in exonerating fibers from classification as a carcinogen. The protocols for performing those tests have been defined by the European Chemical Bureau (EC 1999). The biopersistence protocols are accepted by the EC for interim use and are being validated in a multicenter ring test. The subcommittee believes that instillation tests are useful for ranking the biopersistence of MVF fibers, but their validation will require data on more fiber types than are presently available. Validation should include the deposition of instilled fibrous material into the alveolar regions of the lung, and correlation of biopersistence of the instilled material (as defined by the investigators) with the development of pathological pulmonary effects.

In spite of the limited data available from these studies, intratracheal instillation of materials remains a popular alternative to inhalation exposure for several practical reasons: small quantities of the test compound can be used, thus reducing waste and increasing safety when hazardous materials are being tested; the technique is inexpensive because it does not require expensive exposure chambers and elaborate vapor or aerosol generation apparatus; complex technical support is not necessary for producing and monitoring vapor or aerosol exposures; and high concentrations of particles or fibers can be administered to the respiratory tract at numerous doses with precise control and measurement.

There are also disadvantages to instillation that stem from the differential distribution in the lung of instilled particles compared with inhaled particles. Instilled particles move to the gravity-dependent portions of the lung because the injected material settles, whereas inhaled airborne particles tend to be well distributed throughout the respiratory system, particularly in the small airways. The high local concentration of instillates or their carrier liquids can cause local tissue damage, particularly at high particle or fiber doses. That can lead to local hemorrhage and even death by mechanisms not directly relevant to the study. The acute inflammatory response that develops in response to the high particle burden and liquid suspension of the carrier could actually contribute to the formation of lesions observed in instillation studies. In contrast, the inhalation technique avoids these local and regional overload effects because the lungs of the exposed animals do not receive the full bolus of particles in one dose. Inhalation models best simulate human exposure because only respirable particles reach the lung parenchyma. Instillation techniques, in contrast, can result in the delivery of nonrespirable (large) particles to the alveolar regions, where they normally would not deposit.

Instillation is an acceptable form of dosing in many cases and might be the only practical mean of dosing but it cannot substitute for a properly performed inhalation study. This type of toxicity study has been used in fiber clearance and biopersistence studies.

INTRACAVITARY INJECTION

Intracavitary tests, such as intraperitoneal and intrapleural fiber-injection studies, are conducted primarily in rats. In many cases, rats are given abdominal or pleural injections of a bolus that contains from 10^6-10^9 fibers and are then evaluated at the end of their lifespan or when a tumor is identified. These tests are known to produce a high incidence of mesotheliomas. Intracavitary models have been advocated as relatively inexpensive and highly sensitive tests to predict the carcinogenicity of fibers (Stanton et al. 1981; Pott 1980). However, the route of administration bypasses all natural defenses, and a single dose (or a few repeated doses) early in life might not necessarily produce the physiological responses that would be observed at lower doses and longer exposures. There is considerable concern that intracavitary models can give false-positive results, even for the prediction of mesothelioma risk, and there is no agreement over their predictive value for lung cancer. The subcommittee agrees with a WHO scientific panel's conclusion that the intraperitoneal model should not be used for quantitative risk assessment or for comparing relative hazards posed by different fibers (WHO 1992).

CONCLUSIONS

It appears reasonable to conclude that extrapolations from animal toxicity data to humans for MVF can best be made when experimental animals are exposed to fibers via inhalation. Studies using instilled doses are valuable insofar as they provide a rough estimate of the pulmonary toxicity of materials, but they should not be used for hazard assessments when setting exposure limits.

Intracavitary exposures, via either intraperitoneal or intrapleural injections, can produce a high incidence of mesotheliomas. Such exposures have been advocated as relatively inexpensive and highly sensitive tests to predict the carcinogenicity of inhaled fibers (Pott et al. 1989). However, this route of administration bypasses all natural pulmonary defenses, and the single dose (or a few repeated doses) is not physiologically based and can create an overload in the peritoneal or pleural cavity. Intracavitary tests can also yield false-positive results, for the assessment of lung cancer and mesothelioma risks. The WHO consultation (WHO 1992) concluded that the intracavitary model should not be used for quantitative risk assessment or for hazard evaluation of fibers.

Of the three types of tests that can be used to screen for fiber toxicity—inhalation, instillation, and intracavitary—one might be more advantageous than another. Intracavitary tests are not recommended because of the numerous deficiencies discussed above. Results of instillation studies are qualitatively similar to those of inhalation studies (Henderson et al. 1995) and are adequate for short-term estimates of toxicity and fiber-clearance studies, but they cannot substitute for inhalation models for setting dose levels. Short-term inhalation testing should be used for estimating toxicity, evaluating mechanisms, and setting doses for subchronic or chronic inhalation studies. With regard to the latter goal, it is likely that the data generated from short-term inhalation tests could be used to set dose levels for 90-day inhalation studies, thus obviating costly 2-week or 28-day dose-setting inhalation studies.

ATTACHMENT 4

SUMMARY OF PUBLISHED MMVF CONSUMER EXPOSURE DATA

Reference	Sample Description	Sampling Methodology			N	Exposure Levels (f/cc)	
		Micro-scope	Fiber Definition[a]	Type of Fibers		Average[b]	Maximum[c]
Schneider et al. (1996) *(1)*	Personal samples from 5 school children, 5 retired persons, 5 office workers, and 5 taxi drivers	SEM	WHO	Non-asbestos, non-gypsum inorganic fibers	80	0.0060	0.0171 (95%)
Miller et al. (1995) *(2)*	Fiber levels 24 hours after installation of MMVF in 14 homes	SEM	NIOSH 7400B	MMVF	14	0.0060	0.0120
		PCOM	NIOSH 7400B	All fibers	14	0.0020	0.0070
Tiesler et al. (1993) *(3)*	Office buildings, schools, privates houses, and laboratories with visible, uncoated MMVF	SEM	WHO	"Product fibers"	134	0.0006	0.0057
Fischer (1993) *(4)*	7 offices, 1 school, and 1 dwelling with MMVF ceiling boards are in direct contact with indoor air, plus 6 buildings with health complaints	SEM	WHO	"Product fibers"	150	0.0003	0.0018 (95%)
Jacob et al. (1992) *(5)*	Work area the night after installation of glass wool batt or blown insulation	PCOM	NIOSH 7400B	Glass fibers	53	0.0001	0.0009
NIOSH (1991a) *(6)*	Office building with health complaints after work disturbance of fibrous glass insulation	PCOM	NIOSH 7400	Glass fibers	5	<0.0030 (LOD)	<0.0030 (LOD)
NIOSH (1991b) *(7)*	Public school with health complaints; fibrous glass lined ventilation system	PCOM	NIOSH 7400	All fibers	12	<0.0050 (LOD)	0.0050
Schneider (1990) *(8)*	105 rooms containing MMVF ceiling tiles in Danish nurseries, kindergartens/ schools, offices	PCOM	diam. < 3μm	MMVF	105	0.0001	0.0016
Jaffrey et al. (1990a) *(9)*	Living area of house, within one week after attic installation of MMVF insulation	TEM	diam.: < 3μm length: >5 μm, <100μm	MMVF	10	<0.0029	<0.0050
Jaffrey et al. (1990b) *(10)*	1st floor of house, immediately after "major disturbance" of attic insulation.	TEM	diam.: < 3μm length: >5 μm, <100μm	MMVF	11	<0.0010	<0.0020

Reference	Sample Description	Sampling Methodology			N	Exposure Levels (f/cc)	
		Microscope	Fiber Definition[a]	Type of Fibers		Average[b]	Maximum[c]
Gaudichet et al. (1989) *(11)*	Buildings with MMVF insulation or ventilation surface materials	PCOM	diam. < 3μm	MMVF	69	0.0001	0.0062
Jaffrey et al. (1989) *(12)*	1st floor of house, after "major disturbance" of attic MMVF insulation	TEM	diam.: < 3μm length: >5 μm, <100μm	MMVF	8	<0.0020	0.0030
	Living area of house, within one week after attic installation of MMVF insulation				11	0.0099	0.0600
Dodgson et al. (1987) *(13)*	Living areas of houses during installation or disturbance of MMVF attic insulation	SEM	WHO	All fibers	30	0.0045	0.0232
	Same houses; measurements before and after (24 hrs. or 7 days) installation or disturbance				40	<0.0002	<0.0052
Nielsen (1987) *(14)*	140 rooms with MMVF acoustical ceilings	PCOM	Danish NIOSH method (not described)	All MMVF fibers	140	0.0001[d]	0.0013
van der Wal et al. (1987) *(15)*	Living areas of houses one day after installation of blown in glass or mineral wool insulation.	PCOM	WHO	Mineral fibers	8	0.0039	0.0100
Marfels & Spurny (1987) *(16)*	"Representative results" from private houses older than 15 years in Germany	SEM	length >5μm	Non-asbestos mineral fibers	6	0.0023	0.0050
Rindel et al (1987) *(17)*	12 kindergartens in Denmark with MMVF ceiling boards	PCOM	WHO	MMVF	36	0.0001	0.0002
Schneider (1986) *(18)*	11 randomly selected schools with mechanical ventilation in Copenhagen[e]	PCOM	WHO	All fibers not positively identified as non-MMVF	11	0.0001	0.0002
Altree-Williams & Preston (1985) *(19)*	22 office and plant buildings	SEM	WHO	Non-asbestos mineral fibers	193	0.0019	0.0130

Reference	Sample Description	Sampling Methodology			N	Exposure Levels (f/cc)	
		Micro-scope	Fiber Definition[a]	Type of Fibers		Average[b]	Maximum[c]
Schneider (1984) *(20)*	Kindergartens and offices required to be measured by local inspectorate because of problems attributed to MMVF; ceilings consisting of hard MMVF boards or batts	PCOM	WHO	All fibers not positively identified as non-MMMF	7	0.0133[f]	0.0840
Esmen et al. (1980) *(21)*	Estimation of indoor fiber concentrations based on measurements of entrainment of MMMF from medium grade commercial air filters	PCOM	aspect ratio of 3 or greater	all fibers	42	0.0001 (after day 1)	0.0010 (day1)
Balzer (1976) *(22)*	Glass fiber concentrations in ventilation systems lined with fibrous glass	PCOM	Not defined	All glass fibers	37	0.0087	0.0020
Balzer et al. (1971) *(23)*	3 buildings on U. Cal (Berkeley) campus with air transmission systems lined with fibrous glass	PCOM	Not defined	All glass fibers	n.a.	0.0002	0.0006
	10 other buildings with air transmission systems lined with fibrous glass				n.a.	0.0036	0.0090

NOTES

a. Whenever possible, data for respirable fibers is presented. The NIOSH 7400B counting rules include fibers with a diameter <3 µm, a length ≥ 5 µm, and an aspect ratio greater than 5. The WHO criteria for respirable fibers are a diameter <3 µm, a length ≥ 5 µm, and an aspect ratio greater than 3.

b. Unless otherwise indicated, the average concentrations presented are the arithmetic means.

c. Studies that report 95% upper confidence limits rather than maximum exposures are indicated with a "95%" in parentheses.

d. This study reports average concentrations for 9 types of ceiling categories, but does not indicate the number of measurements in each category. The average value presented in the Table above represents the average of the 9 category averages, which assumes equal number of measurements in each category.

e. This study also reported another set of data for 5 schools and one office that were previously reported in the Schneider (1984) study described below.

f The mean is 0.0015 f/cc when the outlier maximum measurement of 0.084 f/cc is excluded.

ATTACHMENT 4

Study

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Study

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